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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,081	11/13/2003	David H. Coy	00537-164003	7933

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DAWN JANELLE AT
BIOMEASURE INC.
27 MAPLE STREET
MILFORD, MA 01757

EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,081	COY ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present application has been transferred from former Examiner Zhang to the present Examiner. The previous restriction requirement and response are noted, but are vacated.

A substantial search burden remains with present application, because Applicant, like so many other researchers, is tweaking with a known peptide AND the only 'fixed' amino acids within the broad formula's of claim 18 and 23 are already known to exist there – not novel. Thus, a search of these fixed points with X's at the other variables results in an individual compound by compound search/examination of each potential alteration at the other loci which Applicant has modified. Therefore, unless and until Applicant establishes on the written record a substantial, contiguous, core structure, bearing modification, which Applicant himself has searched or is confident is novel, which will this Office to then run a search thereof without burden and cover some of the innumerable number of species at the other modified loci – this Examiner has no alternative but to require an election of a single modified somatostatin peptide antagonist as the invention (NOT species) – as each of these modified peptides are deemed distinct – absent evidence to the contrary a art found on any one, in turns renders obvious ALL other species.

For instance, the somatostatin antagonists, as claimed, are a minimum of 7 residues, up to 8 (one loci being optional). A substantial, contiguous, core structure need constitute at least 50% of said structure (e.g. 4 fixed amino acids), absent some other modification that Applicant does not deem the art has contemplated (which the search could focus thereon) – e.g. modification of one loci to include a specific, unnatural amino acid (e.g. residue 2, as beta-Nal). So, by example, Applicant could amend the formulas of claim 18 and 23 to be:

A1-A2-A3-D-Trp-Lys-Thr(Bzl)-Cys-A8-R3, wherein A1-3 and A8 are as defined in claim 23. This leaves a substantial core structure of 4 residues (which Applicant may wish to pre-search for prior art thereto), which the Office may coextensively search with X variables at the A loci (A1-A3 and A8). However, should art be found on the core, and be a somatostatin antagonist, said art will be applied, where the other limitations at the X residues are either taught or obvious variations thereof.

This Examiner hopes the above has helped Applicant understand the Office's burden in the search of well-known modified compounds and how to craft formulas in such a way to avoid burden, yet garner greater breadth than a single distinct compound of said formula. Applicant may telephone the Examiner if necessary before responding hereto.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 18-31 and 44, drawn to formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 514, subclass 2.

II. Claim 32 and 38, drawn to a method of promoting the release of growth hormone, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin

antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

III. Claim 33 and 39, drawn to a method of promoting the release of insulin, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

IV. Claim 34 and 40, drawn to a method of enhancing wound healing, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

V. Claim 35 and 41, drawn to a method of promoting angiogenesis, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

VI. Claim 36 and 42, drawn to a method of imaging cells having somatostatin receptors, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

VII. Claim 37 and 43, drawn to a method of eliciting an antagonist effect from a somatostatin receptor, using ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure; classified in class 424, subclass 1.69+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, namely ANY of the distinct oligopeptides from the formulas directed to distinct somatostatin antagonists, said formulas bearing no substantial core structure.

Inventions II-VII are directed to different methods of use, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not necessarily required for Group II, restriction for examination purposes as indicated is proper.

Requirement for a Single Oligopeptide Election

The oligopeptides, as fully discussed at the outset, do not contain a substantial, contiguous, distinguishable core structure/sequence that runs through them respectively, upon which a coextensive search of all such oligopeptides stemming from said formula may be conducted without an undue burden. Thus an individual sequence and/or structure search is required of each and every potential oligopeptide form the innumerable number thereto. Therefore, irrespective of which of Group I-VII is the elected invention, Applicant is required elect a single oligopeptide to which the invention (group) will be examined on the merits as drawn to (unless the claims be amended in line with the suggestion outlined at the outset, and the written record clarified to guide the Examiner to a core structure which would allow a coextensive search of said formula compounds without an undue burden). **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/21/2007